

Customer Information
BuckyDiagnost Diagnostic X-Ray System

Technique parameters (kV, mA or mAs) may differ from those expected by user.

January 6, 2011

Subject: BuckyDiagnost/Optimus X-Ray Generator systems

Dear Director of Radiology, Manager of Biomedical Engineering or Risk Management:

A problem has been detected in the Optimus X-Ray Generator used in the Philips BuckyDiagnost X-Ray System, which under certain circumstances could result in different levels of patient radiation exposure than was intended by the user. In some cases, an additional exposure may be needed in order to obtain an image of desired quality.

This Customer Information is intended to inform you about:

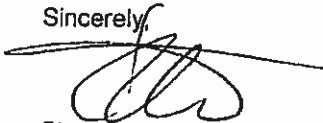
- what the problem is and under what circumstances it can occur
- the actions that you as a user of the equipment can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

If you need any further information or support concerning this issue, please contact your local Philips representative:

Philips Healthcare Call Center at 800-722-9377 #5 (then follow prompts); or
Bob Pettis at 425-487-7469

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Steve Lorenc
SVP & GM Diagnostic X-Ray
Philips Healthcare



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AFFECTED PRODUCTS	BuckyDiagnost Diagnostic X-Ray systems with an Optimus Generator
PROBLEM DESCRIPTION	<p>In manual exposure mode, if the exposure switch is pressed at the same time as one of the technique buttons, it is possible that one of the technique parameters (kV, mA or mAs) may continue to ramp up or down, resulting in a higher or lower x-ray exposure than intended. An additional exposure may be needed in order to obtain an image of desired quality.</p> <p>While no injury is expected to result from a single incorrect diagnostic x-ray exposure, unnecessary radiation exposure is not consistent with good ALARA practices.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	All BuckyDiagnost / TraumaDiagnost systems with Optimus X-ray generator.
ADVICE ON ACTIONS BY CUSTOMER / USER	In order to avoid this problem, whenever you manually change the exposure parameters, make sure that the desired exposure values are displayed and you have released the technique button BEFORE you start the exposure by pressing the exposure switch. This is an interim solution until the software is corrected.
ACTIONS PLANNED BY PHILIPS	A Field Change Order (FCO) will be issued to resolve the problem by updating the system software. These will be identified as FCO-70400041 / FCO-70400042 (BuckyDiagnost) and FCO-72000010 / FCO-72000011 (TraumaDiagnost) and will be installed free of charge. You will be contacted by Philips for Implementation of this FCO.
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p>Philips Healthcare Call Center at 800-722-9377 #5 (then follow prompts) or Bob Pettis at 425-487-7469.</p>

